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Please find below and/or attached an Office communication concerning this application or proceeding.



### DETAILED ACTION

Receipt is acknowledged of applicant's Response filed 11/15/04.

#### ***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-22, 27 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardarelli et al. US 4,400,374 (Cardarelli '374), in view of Cardarelli et al. US 3,590,119 (Cardarelli '119).

Cardarelli '374 teaches a composition for controlled release of compounds from a dispenser including thermoplastic polymer matrix or thermoset matrix (see abstract; and column 3, lines 48-64). The compounds are selected from trace nutrient, plant growth regulators, nematicides, insecticides, molluscicides, cercariacides, aquatic larvicides, and combinations thereof; and are dispersed through the polymer matrix (column 4, lines 4-42; column 5, lines 5-15, lines 30-43; column 7, lines 4-12 and claim 10). The composition further comprises additives, such as filler (column 13, lines 28-41). The composition also comprises porosigen (diatomaceous earth) (column 15, lines 1-67). The composition can be prepared by mixing the components and then cut, chop, or

ground to achieve suitable shape and size (column 17, lines 67 through column 18, lines 1-37). The thermoplastic polymer includes copolymers or terpolymers (column 7, lines 38-68).

Cardarelli '374 does not teach cycloolefin that is a norbornene-ethylene copolymer. However, Cardarelli '119 teaches a controlled release rubber matrix composition comprising larvicide or insecticide (active substance) (column 3, lines 50-73; and example 1). The matrix is made of interpolymers, such as terpolymers of ethylene, including ethylene, propylene and copolymer of ethylene norbornene (column 5, lines 56-68). The composition can be prepared by mill bonding and Banbury mixing, where the terpolymer and the active substance are mixed and then mill/ground into a fine or coarse dust or powder (column 4, lines 33-57; and column 7, lines 64-72). Thus, it would have been obvious for one of ordinary skill in the art to modify the controlled-release polymer matrix of Cardarelli '374 using the terpolymers including ethylene, propylene and ethylene norbornene in view of the teachings of Cardarelli '119, because Cardarelli '374 teaches a composition that exhibits long release duration (column 8, line 31), which can last for days, months, and even years (see abstract), because Cardarelli '119 teaches the controlled release rubber matrix is relatively safe and non-toxic to humans and higher animal forms, while they are storage stable and effective for indefinite periods of time (column 4, lines 42-45), and because Cardarelli '119 that lower dosages of the compounds over longer periods comparing to conventional composition (column 4, lines 1-7, lines 58-75). The expected result would be a stable controlled

release polymer matrix comprising active compounds that is useful in agrochemical field.

Claims 19 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardarelli '374, in view of Cardarelli '119 and Kanda et al. US 4,923,894.

Cardarelli '374 and Cardarelli '119 are relied upon for the reasons stated above. The references do not explicitly teach the average diameter of the particle.

Kanda teaches a polymeric microparticle encapsulating active substance having pesticidal activity (see abstract, and column 1, lines 6-18). The polymeric microparticle has an average particle size of 0.01 to 250 microns (column 2, lines 57-60). Thus, it would have been obvious for one of ordinary skill in the art to modify the polymer matrix of Cardarelli '374 and Cardarelli '119 to have the average particle size of 0.01 to 250  $\mu\text{m}$  in view of the teachings of Kanda, because Cardarelli '374 and Cardarelli '119 teach the polymer matrix can be cut, chopped or ground to achieve a suitable size, and because Kanda teaches polymeric microparticle having average particle size of 0.01-250  $\mu\text{m}$  for retaining good dispersibility, reactivity and stability (column 2, lines 59-61). The expected result would be a stable controlled release polymer matrix comprising active compounds that is useful in agrochemical field.

Claims 23-25, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardarelli '374, in view of Cardarelli '119 and Jacobs et al. WO 98/27125 (equivalent to US 6,365,686, hereafter Jacobs '686).

Cardarelli '374 and Cardarelli '119 are relied upon for the reasons stated above. The references are silent as to the teaching of the physical/chemical properties of the thermoplastic polymer. However, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). However, to be more significant, Jacobs '686 teaches cycloolefin copolymers such as ethylene norbornene that has a glass transition temperatures of from -50°C to 220°C, an average molar masses of 1000 to 10,000 g/mol, and a viscosity of from 10 to 1000 ml/g (column 24, lines 1-67). Thus, it would have been obvious for one of ordinary skill in the art to modify the polymer matrix of Cardarelli '374 and Cardarelli '119 using the ethylene-norbornene copolymer in view of the teaching of Jacobs '686, because Cardarelli '119 teaches the polymer matrix is made of terpolymer including copolymer of ethylene norbornene (column 5, lines 60-68), and because Jacobs '686 teaches cycloolefin copolymers are suitable for use as thermoplastic molding composition of any size and shape (column 1, lines 13-18; and column 25, lines 43-49). The expected result would be a stable controlled release polymer matrix comprising active compounds that is useful in agrochemical field.

Claims 30 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardarelli '374, in view of Cardarelli '119 and Eby, III US 5,409,905.

Cardarelli '374 and Cardarelli '119 are relied upon for the reasons stated above. The references do not explicitly teach the use of the polymer matrix in a pharmaceutical composition. However, Cardarelli '374 teaches thermoplastic polymer matrix use to control release of trace nutrient including zinc (column 4, lines 7-11). It is the position of the examiner that zinc is known for the treatment of cold. Evident by the teaching of Eby (see abstract). Eby teaches the use of zinc for the treatment of common cold (see abstract). Thus, it would have been obvious for one of ordinary skill in the art to modify the polymer matrix of Cardarelli '374 and Cardarelli '119 for the slow release of zinc useful for the treatment of common cold in view of the teaching of Eby, because Eby teaches the use of zinc in a pharmaceutical composition that has a pleasant taste and slowly release zinc over a prolong period of time (column 10, lines 22-30), because Eby teaches a zinc composition that is non-toxic, thermally, chemically, and flavor stable for over long period of storage time (column 7, lines 60-65), because Cardarelli '374 teaches a composition that exhibits long release duration (column 8, line 31), which can last for days, months, and even years (see abstract), because Cardarelli '119 teaches the controlled release rubber matrix is relatively safe and non-toxic to humans and higher animal forms, while they are storage stable and effective for indefinite periods of time (column 4, lines 42-45). The expected result would be a stable controlled release polymer matrix comprising active compounds that is useful in pharmaceutical art.

***Response to Arguments***

Applicant's arguments filed 11/15/04 have been fully considered but they are not persuasive. The 102(b) rejection by Cardarelli '119 has been withdrawn in view of applicant's argument.

Applicant argues that both, Cardarelli '374 and '119 do not teach the cycloolefin copolymer (COC). The EPDM rubber of the Cardarelli '119 is a terpolymer of Ethylene-propylene-diene, while the COC of the present invention is a bipolymer. However, the examiner is unable to determine the unexpected and/or unusual results between the claimed rubber, norbornene-ethylene copolymer and propylene and ethylene norbornene taught by Cardarelli '119 (see column 5, lines 56-68). The burden is shifted to applicant to provide data showing unexpected results, and/or data establishing detrimental effect in the desirability to obtain the claimed invention in use the of terpolymer verses bipolymer, because Cardarelli '119 recognizes all the properties desired by the applicant including: 1) useful to public health authorities (column 1, line 62); 2) not harmful to other fish and animal life in the concentrations suitable for killing larvae; 3) provides an unusually long term larvicidal action; 4) capable of molecular release of the organic toxicant into water at controlled rates thereby making it possible to maintain at the surface of the treated water the lowest lethal larvicidal levels of toxicant over very long periods of time; 5) safe and non-toxic to humans and higher animal forms; 6) remain storage stable and effective for indefinite periods of time (column 3, lines 45-58; and column 4, lines 44-46).



Applicant argues that Kanda does not teach the COC of the present invention. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Kanda is cited solely for the teaching of a polymeric microparticle encapsulating active substance having pesticidal activity, in combination with Cardarelli '374 and '119.

Applicant argues that there is no reason for one skilled in the art to combine Cardarelli '374 in view of Cardarelli '119 and Jacobs '686. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Jacobs '686 is relied upon for the teaching of the known properties of COC, such as norbornene-ethylene.

Applicant argues that Eby does not cure the deficiencies of Cardarelli '374 and Cardarelli '119. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the

structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Eby is cited solely for the teaching of zinc that can be used in the treatment of common cold.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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